

REMARKS/ARGUMENTS

The Office Action mailed June 9, 2006 has been reviewed and carefully considered. Claims 12-22 are pending in this application, with claims 12 and 22 being the only independent claims. Reconsideration of the above-identified application in view of the following remarks is respectfully requested.

Priority Claim

It is pointed out that the certified copy of the priority document was in fact filed together with the application, as can be derived from the enclosed copy of the filing receipt. An acknowledging confirmation is solicited.

Amendments to the Specification

The amendment to the specification addresses the objection raised by the Examiner.

Claim Amendments

Amended independent claim 1 includes a more detailed explanation of the inventive subject matter. The tubular guide sleeve is now claimed as "being intrinsically stable in an empty state to maintain the existing tissue passage and being separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve". Support for the newly added limitations is found at page 2 lines 5-8, as well as page 6 last paragraph of the original disclosure.

Claim 22 is similarly amended.

As proposed by the Examiner, in amended claim 16 "and" is changed to "or".

Claims 13 and 17 are amended to correct obvious errors.

Claims 14-15 and 18-21 remain unchanged.

Claim Rejections

Claims 12-16, 18-20, and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,431,676 (Dubrul).

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul in view of U.S. Patent No. 6,939,327 (Hall).

Claim 21 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul in view of U.S. Patent No. 4,687,469 (Osypka).

Amended independent claim 1 recites "said tubular guide sleeve being intrinsically stable in an empty state to maintain the existing tissue passage and being separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve".

Dubrul fails to disclose the cited limitation because Dubrul fails to disclose that the sheath which is separable is also intrinsically stable in an empty state to maintain the tissue opening.

Dubrul discloses a device for providing percutaneous access to an internal operative site during a surgical procedure. As can be best seen in Figs. 1, 4, and 9, the device comprises an elongate dilation member 10 (which is to be dilated), at least one expansion member 12 for dilating the dilation member 10, and a trocar valve 16 (col. 9, lines 1-4). The dilation member 10 comprises a tubular braid 20 with braid filaments, in particular a mesh of individual non-elastic filaments (col. 6, lines 53-57). The tubular braid 20 is covered with a removable sheath 30 having a handle 32 at

its proximal end (col. 9, lines 22-24). After the dilation member 10 has been placed in the opening of the human body, the expansion member 12 can be inserted into it causing radial expansion of the tubular braid 20. The expansion member 12 will optionally split the sheath 30 upon insertion (col. 11, lines 12-29). The sheath 30 protects the tubular braid 20 during initial insertion of the dilation member 10 into the body of the patient, but is removed from the braid 20 after the dilation member 10 is in place. Preferably, the sheath 30 is weakened along an axial line to facilitate splitting of the sheath 30 at some point during the procedure (col. 7, lines 14-19).

However, Dubrul fails to disclose, teach or suggest the combined limitations of a tubular guide sleeve "being intrinsically stable in an empty state to maintain the existing tissue passage and being separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve". As a result of these features, the tubular guide sleeve according to the invention can first maintain the opening of the body without any additional support elements, and the whole guide sleeve (all separated parts) can then be completely removed from the opening after the dilatation pin has been inserted.

To the contrary, the only stable element in the device of Dubrul, which maintains the opening once the dilation member 10 is inserted, is the tubular braid 20. The protective sheath 30, however, is not intrinsically stable at all. On the other hand, the tubular braid 20 is not separable along a line and remains within the body opening during treatment. Therefore, this device differs substantially from the device as claimed in amended claim 12 in regard of the general structure and its functioning, and a person skilled in the art could not derive any suggestion from Dubrul toward the inventive construction.

Hall discloses another peel-away sheath, and Osypka shows a device for slitting introducers for pacemaker electrodes, but both documents do not exhibit any hint towards the present invention according to amended claim 12.

The same argumentation applies to claim 22.


Therefore, amended independent claims 12 and 22 are allowable over the prior art of record.

Dependent claims 13-21, each being dependent on independent claim 12, are allowable for the same reasons expressed above with respect to independent claim 12, as well as for the additional recitations therein.

In view of the above amendments and remarks, the application is now deemed to be in condition for allowance and notice to that effect is solicited.

Respectfully submitted,

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